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EXAMINER	
DAVIS, MINH TAM B	

ART UNIT	PAPER NUMBER
1642	8

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/724,524	Applicant(s) PRESTA ET AL.	
	Examiner MINH-TAM DAVIS	Art Unit 1642	

-- The MAILING DATE f this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *6-19* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant cancels claims 1-5 and adds new claims 6-19.

The addition of new claims 6-19 requires new restriction.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 6-12, drawn to a method for diagnosis of a pathological condition characterized by the over-expression of the human neurotrophin receptor TrkA, comprising contacting a sample with an antibody specific for trkA, classified in class 435, subclass 7.1. It is noted that claim 6 is an improper implied Markush claim, since it is clearly meant to encompass a method for diagnosing diseases by detecting not only different neurotrophin receptors, having different structure and characteristics, but also different diseases characterized by either the over-expression or under-expression of said receptors. Further, MPEP 2173.05(h) provides that when the Markush group occurs in a claim reciting a process or a combination it is sufficient if the members of the group are disclosed in the specification to possess at least one property in common which is responsible for their function in the claimed relationship and it is clear from their very nature or from the prior art that all of them possess this property. The members of the implied Markush groups recited in claim 6 do not share a common structure, nor do they function by a common mechanism.

Group II. Claims 6-12, drawn to a method for diagnosis of a pathological condition characterized by the over-expression of the human neurotrophin receptor

TrkB, comprising contacting a sample with an antibody specific for trkB, classified in class 435, subclass 7.1. It is noted that claim 6 is an improper implied Markush claim, since it is clearly meant to encompass a method for diagnosing diseases by detecting not only different neurotrophin receptors, having different structure and characteristics, but also different diseases characterized by either the over-expression or under-expression of said receptors. Further, MPEP 2173.05(h) provides that when the Markush group occurs in a claim reciting a process or a combination it is sufficient if the members of the group are disclosed in the specification to possess at least one property in common which is responsible for their function in the claimed relationship and it is clear from their very nature or from the prior art that all of them possess this property. The members of the implied Markush groups recited in claim 6 do not share a common structure, nor do they function by a common mechanism.

Group III. Claims 6-12, drawn to a method for diagnosis of a pathological condition characterized by the over-expression of the human neurotrophin receptor TrkC, comprising contacting a sample with an antibody specific for trkC, classified in class 435, subclass 7.1. It is noted that claim 6 is an improper implied Markush claim, since it is clearly meant to encompass a method for diagnosing diseases by detecting not only different neurotrophin receptors, having different structure and characteristics, but also different diseases characterized by either the over-expression or under-expression of said receptors. Further, MPEP 2173.05(h) provides that when the Markush group occurs in a claim reciting a process or a combination it is sufficient if the members of the group are disclosed in the specification to possess at least one property

in common which is responsible for their function in the claimed relationship and it is clear from their very nature or from the prior art that all of them possess this property. The members of the implied Markush groups recited in claim 6 do not share a common structure, nor do they function by a common mechanism.

Group IV. Claims 6-12, drawn to a method for diagnosis of a pathological condition characterized by the under-expression of the human neurotrophin receptor TrkA, comprising contacting a sample with an antibody specific for trkA, classified in class 435, subclass 7.1. It is noted that claim 6 is an improper implied Markush claim, since it is clearly meant to encompass a method for diagnosing diseases by detecting not only different neurotrophin receptors, having different structure and characteristics, but also different diseases characterized by either the over-expression or under-expression of said receptors. Further, MPEP 2173.05(h) provides that when the Markush group occurs in a claim reciting a process or a combination it is sufficient if the members of the group are disclosed in the specification to possess at least one property in common which is responsible for their function in the claimed relationship and it is clear from their very nature or from the prior art that all of them possess this property. The members of the implied Markush groups recited in claim 6 do not share a common structure, nor do they function by a common mechanism.

Group V. Claims 6-12, drawn to a method for diagnosis of a pathological condition characterized by the under-expression of the human neurotrophin receptor TrkB, comprising contacting a sample with an antibody specific for trkB, classified in class 435, subclass 7.1. It is noted that claim 6 is an improper implied Markush claim,

since it is clearly meant to encompass a method for diagnosing diseases by detecting not only different neurotrophin receptors, having different structure and characteristics, but also different diseases characterized by either the over-expression or under-expression of said receptors. Further, MPEP 2173.05(h) provides that when the Markush group occurs in a claim reciting a process or a combination it is sufficient if the members of the group are disclosed in the specification to possess at least one property in common which is responsible for their function in the claimed relationship and it is clear from their very nature or from the prior art that all of them possess this property. The members of the implied Markush groups recited in claim 6 do not share a common structure, nor do they function by a common mechanism.

Group VI. Claims 6-12, drawn to a method for diagnosis of a pathological condition characterized by the under-expression of the human neurotrophin receptor TrkC, comprising contacting a sample with an antibody specific for trkC, classified in class 435, subclass 7.1. It is noted that claim 6 is an improper implied Markush claim, since it is clearly meant to encompass a method for diagnosing diseases by detecting not only different neurotrophin receptors, having different structure and characteristics, but also different diseases characterized by either the over-expression or under-expression of said receptors. Further, MPEP 2173.05(h) provides that when the Markush group occurs in a claim reciting a process or a combination it is sufficient if the members of the group are disclosed in the specification to possess at least one property in common which is responsible for their function in the claimed relationship and it is clear from their very nature or from the prior art that all of them possess this property.

The members of the implied Markush groups recited in claim 6 do not share a common structure, nor do they function by a common mechanism.

Group VII. Claims 13-16, drawn to a method for diagnosis of a pathological condition characterized by the over-expression of the human neurotrophin receptor TrkA, comprising detecting the presence of trkA transcript, classified in class 435, subclass 6. It is noted that claim 13 is an improper implied Markush claim, since it is clearly meant to encompass a method for diagnosing diseases by detecting not only transcripts of different neurotrophin receptors, having different structure and characteristics, but also different diseases characterized by either the over-expression or under-expression of said receptors. Further, MPEP 2173.05(h) provides that when the Markush group occurs in a claim reciting a process or a combination it is sufficient if the members of the group are disclosed in the specification to possess at least one property in common which is responsible for their function in the claimed relationship and it is clear from their very nature or from the prior art that all of them possess this property. The members of the implied Markush groups recited in claim 13 do not share a common structure, nor do they function by a common mechanism.

Group VIII. Claims 13-16, drawn to a method for diagnosis of a pathological condition characterized by the over-expression of the human neurotrophin receptor TrkB, comprising detecting the presence of trkB transcript, classified in class 435, subclass 6. It is noted that claim 13 is an improper implied Markush claim, since it is clearly meant to encompass a method for diagnosing diseases by detecting not only transcripts of different neurotrophin receptors, having different structure and

characteristics, but also different diseases characterized by either the over-expression or under-expression of said receptors. Further, MPEP 2173.05(h) provides that when the Markush group occurs in a claim reciting a process or a combination it is sufficient if the members of the group are disclosed in the specification to possess at least one property in common which is responsible for their function in the claimed relationship and it is clear from their very nature or from the prior art that all of them possess this property. The members of the implied Markush groups recited in claim 13 do not share a common structure, nor do they function by a common mechanism.

Group IX. Claims 13-16, drawn to a method for diagnosis of a pathological condition characterized by the over-expression of the human neurotrophin receptor TrkC, comprising detecting the presence of trkC transcript, classified in class 435, subclass 6. It is noted that claim 13 is an improper implied Markush claim, since it is clearly meant to encompass a method for diagnosing diseases by detecting not only transcripts of different neurotrophin receptors, having different structure and characteristics, but also different diseases characterized by either the over-expression or under-expression of said receptors. Further, MPEP 2173.05(h) provides that when the Markush group occurs in a claim reciting a process or a combination it is sufficient if the members of the group are disclosed in the specification to possess at least one property in common which is responsible for their function in the claimed relationship and it is clear from their very nature or from the prior art that all of them possess this property. The members of the implied Markush groups recited in claim 13 do not share a common structure, nor do they function by a common mechanism.

Group X. Claims 13-16, drawn to a method for diagnosis of a pathological condition characterized by the under-expression of the human neurotrophin receptor TrkA, comprising detecting the presence of trkA transcript, classified in class 435, subclass 6. It is noted that claim 13 is an improper implied Markush claim, since it is clearly meant to encompass a method for diagnosing diseases by detecting not only transcripts of different neurotrophin receptors, having different structure and characteristics, but also different diseases characterized by either the over-expression or under-expression of said receptors. Further, MPEP 2173.05(h) provides that when the Markush group occurs in a claim reciting a process or a combination it is sufficient if the members of the group are disclosed in the specification to possess at least one property in common which is responsible for their function in the claimed relationship and it is clear from their very nature or from the prior art that all of them possess this property. The members of the implied Markush groups recited in claim 13 do not share a common structure, nor do they function by a common mechanism.

Group XI. Claims 13-16, drawn to a method for diagnosis of a pathological condition characterized by the under-expression of the human neurotrophin receptor TrkB, comprising detecting the presence of trkB transcript, classified in class 435, subclass 6. It is noted that claim 13 is an improper implied Markush claim, since it is clearly meant to encompass a method for diagnosing diseases by detecting not only transcripts of different neurotrophin receptors, having different structure and characteristics, but also different diseases characterized by either the over-expression or under-expression of said receptors. Further, MPEP 2173.05(h) provides that when

the Markush group occurs in a claim reciting a process or a combination it is sufficient if the members of the group are disclosed in the specification to possess at least one property in common which is responsible for their function in the claimed relationship and it is clear from their very nature or from the prior art that all of them possess this property. The members of the implied Markush groups recited in claim 13 do not share a common structure, nor do they function by a common mechanism.

Group XII. Claims 13-16, drawn to a method for diagnosis of a pathological condition characterized by the under-expression of the human neurotrophin receptor TrkC, comprising detecting the presence of trkC transcript, classified in class 435, subclass 6. It is noted that claim 13 is an improper implied Markush claim, since it is clearly meant to encompass a method for diagnosing diseases by detecting not only transcripts of different neurotrophin receptors, having different structure and characteristics, but also different diseases characterized by either the over-expression or under-expression of said receptors. Further, MPEP 2173.05(h) provides that when the Markush group occurs in a claim reciting a process or a combination it is sufficient if the members of the group are disclosed in the specification to possess at least one property in common which is responsible for their function in the claimed relationship and it is clear from their very nature or from the prior art that all of them possess this property. The members of the implied Markush groups recited in claim 13 do not share a common structure, nor do they function by a common mechanism.

Group XIII. Claims 17-19, drawn to a method for diagnosis of a pathological condition characterized by the over-expression of a human neurotrophin comprising

detecting the presence of a labeled polypeptide comprising at least a portion of a neurotrophin receptor TrkA, classified in class 435, subclass 7.1. It is noted that claim 17 is an improper implied Markush claim, since it is clearly meant to encompass a method for diagnosing diseases by detecting not only different polypeptides comprising different neurotrophin receptors, having different structure and characteristics, but also different diseases characterized by either the over-expression or under-expression of different neurotrophins. Further, MPEP 2173.05(h) provides that when the Markush group occurs in a claim reciting a process or a combination it is sufficient if the members of the group are disclosed in the specification to possess at least one property in common which is responsible for their function in the claimed relationship and it is clear from their very nature or from the prior art that all of them possess this property. The members of the implied Markush groups recited in claim 17 do not share a common structure, nor do they function by a common mechanism.

Group XIV. Claims 17-19, drawn to a method for diagnosis of a pathological condition characterized by the over-expression of a human neurotrophin comprising detecting the presence of a labeled polypeptide comprising at least a portion of a neurotrophin receptor TrkB, classified in class 435, subclass 7.1. It is noted that claim 17 is an improper implied Markush claim, since it is clearly meant to encompass a method for diagnosing diseases by detecting not only different polypeptides comprising different neurotrophin receptors, having different structure and characteristics, but also different diseases characterized by either the over-expression or under-expression of different neurotrophins. Further, MPEP 2173.05(h) provides that when the Markush

group occurs in a claim reciting a process or a combination it is sufficient if the members of the group are disclosed in the specification to possess at least one property in common which is responsible for their function in the claimed relationship and it is clear from their very nature or from the prior art that all of them possess this property. The members of the implied Markush groups recited in claim 17 do not share a common structure, nor do they function by a common mechanism.

Group XV. Claims 17-19, drawn to a method for diagnosis of a pathological condition characterized by the over-expression of a human neurotrophin comprising detecting the presence of a labeled polypeptide comprising at least a portion of a neurotrophin receptor TrkC, classified in class 435, subclass 7.1. It is noted that claim 17 is an improper implied Markush claim, since it is clearly meant to encompass a method for diagnosing diseases by detecting not only different polypeptides comprising different neurotrophin receptors, having different structure and characteristics, but also different diseases characterized by either the over-expression or under-expression of different neurotrophins. Further, MPEP 2173.05(h) provides that when the Markush group occurs in a claim reciting a process or a combination it is sufficient if the members of the group are disclosed in the specification to possess at least one property in common which is responsible for their function in the claimed relationship and it is clear from their very nature or from the prior art that all of them possess this property. The members of the implied Markush groups recited in claim 17 do not share a common structure, nor do they function by a common mechanism.

Group XVI. Claims 17-19, drawn to a method for diagnosis of a pathological condition characterized by the under-expression of a human neurotrophin comprising detecting the presence of a labeled polypeptide comprising at least a portion of a neurotrophin receptor TrkA, classified in class 435, subclass 7.1. It is noted that claim 17 is an improper implied Markush claim, since it is clearly meant to encompass a method for diagnosing diseases by detecting not only different polypeptides comprising different neurotrophin receptors, having different structure and characteristics, but also different diseases characterized by either the over-expression or under-expression of different neurotrophins. Further, MPEP 2173.05(h) provides that when the Markush group occurs in a claim reciting a process or a combination it is sufficient if the members of the group are disclosed in the specification to possess at least one property in common which is responsible for their function in the claimed relationship and it is clear from their very nature or from the prior art that all of them possess this property. The members of the implied Markush groups recited in claim 17 do not share a common structure, nor do they function by a common mechanism.

Group XVII. Claims 17-19, drawn to a method for diagnosis of a pathological condition characterized by the under-expression of a human neurotrophin comprising detecting the presence of a labeled polypeptide comprising at least a portion of a neurotrophin receptor TrkB, classified in class 435, subclass 7.1. It is noted that claim 17 is an improper implied Markush claim, since it is clearly meant to encompass a method for diagnosing diseases by detecting not only different polypeptides comprising different neurotrophin receptors, having different structure and characteristics, but also

different diseases characterized by either the over-expression or under-expression of different neurotrophins. Further, MPEP 2173.05(h) provides that when the Markush group occurs in a claim reciting a process or a combination it is sufficient if the members of the group are disclosed in the specification to possess at least one property in common which is responsible for their function in the claimed relationship and it is clear from their very nature or from the prior art that all of them possess this property. The members of the implied Markush groups recited in claim 17 do not share a common structure, nor do they function by a common mechanism.

Group XVIII. Claims 17-19, drawn to a method for diagnosis of a pathological condition characterized by the under-expression of a human neurotrophin comprising detecting the presence of a labeled polypeptide comprising at least a portion of a neurotrophin receptor TrkC, classified in class 435, subclass 7.1. It is noted that claim 17 is an improper implied Markush claim, since it is clearly meant to encompass a method for diagnosing diseases by detecting not only different polypeptides comprising different neurotrophin receptors, having different structure and characteristics, but also different diseases characterized by either the over-expression or under-expression of different neurotrophins. Further, MPEP 2173.05(h) provides that when the Markush group occurs in a claim reciting a process or a combination it is sufficient if the members of the group are disclosed in the specification to possess at least one property in common which is responsible for their function in the claimed relationship and it is clear from their very nature or from the prior art that all of them possess this property. The

members of the implied Markush groups recited in claim 17 do not share a common structure, nor do they function by a common mechanism.

In addition, upon election of any of groups I-XII, further election of the following species is required:

Any one of the diseases recited in claim 9.

Upon election of any of groups I-VI, further election of the following species is required:

Any one of the assay method recited in claim 8.

Upon election of any one of groups VII-XII, further election of the following species is required:

Northern hybridization, *in situ* hybridization or PCR.

Upon election of any of groups XIII-XVIII, Applicant is required to identify the appropriate corresponding neurotrophin(s) recited in claim 19, and elect a single corresponding neurotrophin.

The inventions are distinct, each from each other because of the following reasons:

The methods of groups I-XVIII are distinct from each other because they differ at least in objectives, method steps, reagents and/or dosages, and/or schedules used, response variables and criteria for success.

The species diseases are distinct because they are different diseases with different etiology.

The species assay methods are distinct because they are different methods having different method steps, reagents and/or dosages, and/or schedules used, response variables and criteria for success.

The species Northern hybridization, *in situ* hybridization or PCR are distinct because they are different methods having different method steps, reagents and/or dosages, and/or schedules used, response variables and criteria for success.

Because these inventions are distinct for the reason given above and have acquired a separate status in the art, and because the searches for the groups are not co-extensive, restriction for examination purposes as indicated is proper.

Applicants are required under 35 USC 121 to elect a single disclosed group for prosecution on the merits to which the claims shall be restricted. Applicant is further advised that if Applicant elects a group having species requirement, a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record

showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 USC 103 of the other invention.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendement of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 703-305-2008. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANTHONY CAPUTA can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

MINH TAM DAVIS

May 18, 2002

SUSAN UNGAR, PH.D
PRIMARY EXAMINER